

HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) LEVEL II CODING PROCEDURES

This information provides a description of the procedures the Centers for Medicare & Medicaid Services (CMS) follows in processing HCPCS Level II applications and making coding decisions.

FOR FURTHER INFORMATION CONTACT:

Please submit an inquiry to the HCPCS mailbox at HCPCS@cms.hhs.gov.

A. HCPCS BACKGROUND INFORMATION

Each year in the United States (U.S.), health care insurers process over five billion claims for payment. For Medicare and other health insurance programs to ensure that these claims are processed in an orderly and consistent manner, standardized coding systems are essential. The HCPCS Level II Code Set is one of the standard, national medical code sets specified by the Health Insurance Portability and Accountability Act (HIPAA) for this purpose. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I of the HCPCS is comprised of Current Procedural Terminology (CPT), a numeric coding system maintained by the American Medical Association (AMA). The CPT is a uniform coding system consisting of descriptive terms and codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. These health care professionals use the CPT to identify services and procedures for which they bill public or private health insurance programs. The CPT codes are republished and updated annually by the AMA.

HCPCS Level II is a standardized coding system that is used primarily to identify drugs, biologicals and non-drug and non-biological items, supplies, and services not included in the CPT code set jurisdiction, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office. Because Medicare and other insurers cover a variety of services, supplies, and equipment that are not identified by CPT codes, the HCPCS Level II codes were established for submitting claims for these items. HCPCS Level II codes are also referred to as alpha-numeric codes because they consist of a single alphabetical letter followed by four numeric digits, while CPT codes primarily are identified using five numeric digits.

A. HISTORY

The development and use of Level II of the HCPCS began in the 1980s. Concurrent to the use of Level II codes, there were also Level III codes. HCPCS Level III were developed and used by Medicaid State agencies, Medicare contractors, and private insurers in their specific programs or local areas of jurisdiction. For purposes of Medicare, Level III codes were also referred to as local codes. Local codes were established when an insurer preferred that suppliers use a local code to identify a service, for which there is no Level I or Level II code, rather than using a "miscellaneous or not otherwise classified code."

HIPAA required the Secretary to adopt standards for coding systems that are used for reporting health care transactions. Thus, regulations were published in the Federal Register on August 17, 2000 (65 FR 50312), to implement standardized coding systems under HIPAA. These regulations provided for the elimination of Level III local codes by October 2002, at which time, the Level I and Level II code sets could be used. The elimination of local codes was postponed, as a result of section 532(a) of BIPA, which continued the use of local codes through December 31, 2003.

The regulation that was published on August 17, 2000 (45 CFR 162.1002), to implement the HIPAA requirement for standardized coding systems established the HCPCS Level II codes as the standardized coding system for describing and identifying health care equipment and supplies in health care transactions that are not within the CPT code set jurisdiction. The HCPCS Level II coding system was selected as the standardized coding system because of its wide acceptance among both public and private insurers.

B. AUTHORITY

The Secretary of the Department of Health and Human Services has delegated authority under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to the AMA and CMS to maintain and distribute HCPCS Level I and Level II codes, respectively.

C. HCPCS LEVEL II CODES

The HCPCS Level II coding system is a comprehensive, standardized system that classifies similar products that are medical in nature into categories for the purpose of efficient claims processing. For each alpha-numeric HCPCS code, there is descriptive terminology that identifies a category of like items. These codes are used primarily for billing purposes. For example, suppliers use HCPCS Level II codes to identify items on claim forms that are being billed to a private or public health insurer. Currently, there are national HCPCS codes representing almost 8,000 separate categories of like items or services that encompass products from different manufacturers. When submitting claims, suppliers are required to use one of these codes to identify the items they are billing.

HCPCS is a system for identifying items and certain services. It is not a methodology or system for making coverage or payment determinations, and the existence of a code does not, of itself, determine coverage or non-coverage for an item or service. While these codes are used for billing purposes, decisions regarding the addition, deletion, or revision of HCPCS codes are made independent of the process for making determinations regarding coverage and payment.

With regard to the Medicare program, if specific Medicare coverage or payment indicators or values have not been established for any new HCPCS codes, this may be because a national Medicare coverage determination and/or fee schedule amounts have not yet been established for these items. This is neither an indicator of Medicare coverage or non-coverage. In these cases, until national Medicare coverage and payment guidelines have been established for these codes, the Medicare coverage and payment determinations for these items may be made based on the discretion of the Medicare contractors processing claims for these items.

D. TYPES OF HCPCS LEVEL II CODES

There are several types of HCPCS Level II codes depending on the purpose for the codes and the entity with responsibility for establishing and maintaining them.

HCPCS National Codes

National HCPCS Level II codes are maintained by CMS. CMS is responsible for making decisions about additions, revisions, and deletions to the national alpha-numeric codes. These codes are for the use of all private and public health insurers.

HCPCS Level II applications are reviewed by a group comprised of Federal government employees who represent the major components of CMS, as well as other pertinent Federal agencies such as the Department of Veterans Affairs and the Department of Defense at regularly scheduled meetings to determine whether coding requests warrant a change to the HCPCS Level II national code set. This group of reviewers informs CMS' decisions.

The application and instructions for requesting that CMS add, revise, or discontinue a HCPCS Level II code can be accessed at: <https://mearis.cms.gov/public/home>. CMS may also issue codes based on the needs of its programs or other federal programs.

Dental Codes

Dental codes, or D codes, are a separate category of national codes. The Current Dental Terminology (CDT) is published, copyrighted, and licensed by the American Dental Association (ADA). The CDT lists codes for billing for dental procedures and supplies. While the CDT codes are considered HCPCS Level II codes, decisions regarding the revision, deletion, or addition of CDT codes are made by the ADA, not CMS.

Miscellaneous Codes

National codes also include "miscellaneous/not otherwise classified" codes. These codes are used when a supplier is submitting a bill for an item or service and there is no existing national code that adequately describes the item or service being billed. The importance of miscellaneous codes is that they allow suppliers to begin billing immediately for a service or item as soon as it is allowed to be marketed by the Food and Drug Administration (FDA), even though there is no distinct code that describes the service or item. A miscellaneous code may be assigned by insurers for use during the period of time a request for a new code is being considered under the HCPCS review process. The use of miscellaneous codes also helps avoid the inefficiency and administrative burden of assigning distinct codes for items or services that are rarely furnished or for which few claims are expected to be filed. Because of miscellaneous codes, the absence of a specific code for a distinct category of products does not affect the ability of a supplier to submit claims to private or public insurers.

In those cases, in which a supplier or manufacturer has been advised to use a miscellaneous code because there is no existing code that describes a given product, and the supplier or manufacturer believes that a new code is needed, the supplier or manufacturer may submit a request to modify

the HCPCS in accordance with the established process. The standard process for requesting a revision to the HCPCS Level II codes is explained later in this document.

Other Notable Codes

- The C codes (pass-through) were established to permit implementation of section 201 of the Balanced Budget Refinement Act of 1999. HCPCS C codes are utilized to report drugs, biologicals, magnetic resonance angiography (MRA), and devices used for CMS' Medicare Hospital Outpatient Prospective Payment System (HOPPS). HCPCS C codes are reported for device categories, new technology procedures, and drugs, biologicals, and radiopharmaceuticals that do not have other HCPCS code assignments. Non-OPPS hospitals, Critical Access Hospitals (CAHs), Indian Health Service (IHS) hospitals, and hospitals located in American Samoa, Guam, Northern Mariana Islands, and the Virgin Islands, as well as Maryland waiver hospitals, may report these codes at their discretion.

For information about the HOPPS pass-through process, please visit the HOPPS website: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index>

- The G codes are used to identify professional health care procedures and services that would otherwise be coded in CPT-4 (the current version of CPT codes) but for which there are no CPT-4 codes. CMS does not have an application process for G codes, as they are established internally by CMS to support Medicare claims processing needs. As G codes are part of the national HCPCS Level II code set, they may also be used by non-Medicare insurers.
- The G codes and C codes are considered HCPCS Level II codes and as such, these codes, and changes to them, are included in CMS' HCPCS Level II Updates published by CMS. The code application procedures described in this document are not for use to apply for changes to HCPCS C codes and G codes.
- The Q codes are established to identify drugs, biologicals, and medical equipment or services not identified by national HCPCS Level II codes, but for which codes are needed for Medicare claims processing.
- The K codes are established for use by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) when current national codes do not include the codes needed to implement a DME MAC medical review policy. For example, codes other than the current, existing national codes may be needed by the DME MACs to identify certain product categories and supplies necessary for establishing appropriate regional medical review coverage policies.

Code Modifiers

HCPCS code modifiers are established internally by CMS to facilitate accurate Medicare claims processing. Modifiers are assigned for use when the information provided by a HCPCS code descriptor needs to be supplemented to identify specific circumstances that may apply to an item or

service. For example, the UE modifier is used when the item identified by a HCPCS code is "used equipment," and the NU modifier is used for "new equipment." The HCPCS Level II modifiers are either alpha-numeric or two letters. HCPCS code modifiers are published as part of the HCPCS code set at <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS>. The modifiers appear at the beginning of the file, before alpha-numeric codes.

HCPCS Code Assignment Following Medicare National Coverage Determination (NCD)

Pursuant to section 1862(l)(3)(C)(iv) of the Social Security Act (added by section 731(a) of the Medicare Modernization Act), CMS identifies an appropriate existing code category and/or establishes a new code category to describe the item that is the subject of a National Coverage Determination (NCD).

Effective July 1, 2004, CMS' procedures are as follows:

1. **Assignment of an existing code:** When CMS determines that an item is already identified by an existing HCPCS code category, but was previously not covered, CMS will assign the item to the existing code category and ensure that the coverage indicator assigned to the code category accurately reflects Medicare policy regarding coverage for the item. Section 731 of the MMA does not require that a new code category or a product specific code be created for an item simply because a new coverage determination was made, without regard to codes available in the existing code set.
2. **Assignment of a New Code:** When CMS determines that a new code category is appropriate, CMS will make every effort to establish, publish, and implement the new code at the time the final coverage determination is made.
3. **Assignment of a Miscellaneous Code:** Under certain circumstances, the assignment of an item to a miscellaneous code may be necessary. A number of miscellaneous codes already exist under various headings throughout the HCPCS Level II code set. When a new code is appropriate, but the change cannot be implemented and incorporated into billing and claims processing systems at the time the final NCD decision memorandum is released, an unclassified code may be assigned in the interim, until a new code can be implemented, in order to ensure that claims can be processed for the item. The timing of implementation of new codes relative to the date of the coverage determination depends on a variety of factors, some of which are not within the control of the code set maintainers. One such example is when the timing of the coverage determination is such that the publication deadline for the next update is missed.

E. REQUESTING A REVISION TO THE HCPCS LEVEL II CODES

Anyone may submit a request for modifying the HCPCS Level II national code set. CMS' HCPCS Level II application instructions can be accessed at: <https://mearis.cms.gov/public/home>. As part of the application, the applicant should also submit any descriptive material, including the manufacturer's product literature and information that the applicant thinks would be helpful in furthering CMS' understanding of the medical features of the item for which a coding revision is requested.

Applications that are received and determined by CMS to be complete by the deadline will be considered for inclusion in that cycle. Applications received after the deadline will be considered for the subsequent coding cycle. Applications received by the deadline that are determined to be incomplete will also be declined and the applicant should submit a completed application in a subsequent coding cycle. CMS will make every effort to complete the review within the applicable coding cycle for all timely and complete code applications. However, it should be understood that on the rare occasion a particularly complex or multi-faceted decision requires additional evaluation beyond the timeframe of the coding cycle, CMS maintains the flexibility at its discretion to continue consideration of that application into the next coding cycle. Examples of circumstances under which application consideration may be extended to the next coding cycle may include, but are not limited to, coding considerations that require in-depth clinical or other research and complicated claims adjudication scenarios.

There are three types of coding revisions to the HCPCS that can be requested:

1. That a new code be added. This could include requests to split an existing code category into its components or into subcategories;
2. That the language used to describe an existing code be changed:

When there is an existing code, a request can be made when a stakeholder believes that the descriptor for the code needs to be revised to provide a better description of the category of products represented by the code.

3. That an existing code be discontinued.

When an existing code becomes obsolete or is duplicative of another code, a request can be made to discontinue the code. This could include requests to combine existing codes.

The electronic application intake system, Medicare Electronic Application Request Information System™ ([MEARIS™](#)), is available for HCPCS Level II application submissions. The HCPCS Level II Application form designed for MEARIS™ is similar to the current OMB-approved paper application (CMS-10224, OMB-0938-1042). The CMS HCPCS Level II Modification to Code Set Form can be accessed at: <https://mearis.cms.gov/public/home>.

Moving forward, CMS will only accept HCPCS Level II applications submitted via MEARIS™. Applications submitted to the HCPCS application mailbox will no longer be considered. Within MEARIS™, there are several [resources](#) to support applicants.

Evaluating HCPCS Level II Coding Applications

CMS applies the following criteria to determine when there is no demonstrated need for a new or modified code or the need to remove a code:

1. When an existing code adequately describes the item in a coding request, no new or modified code is established. An existing code adequately describes an item in a coding request when the existing code describes items with the following:

- Functions similar to the item in the coding request.
 - No significant therapeutic distinctions from the item in the coding request.
2. When an existing code describes items that provide almost the same functionality with only minor distinctions from the item in the coding request, the item in the coding request may be grouped with that code and the code descriptor modified to reflect the distinctions.
 3. A code is not established for an item that is used only in the inpatient setting or for an item that is not diagnostic or therapeutic in nature.
 4. A new or modified code is not established for an item that is regulated by the FDA, unless the FDA allows the item to be marketed. Documentation of FDA approval is required to be submitted with the coding request application.
 5. Applications for non-drug items that are not regulated by the FDA and also not yet available in the U.S. market will be considered incomplete and will not be processed.
 6. The determination to remove a code is based on CMS' consideration of whether a code is obsolete (for example, items no longer are used, other more specific codes have been added) or duplicative and no longer useful (for example, new codes are established that better describe items identified by existing codes).

In developing its decisions, CMS uses the criteria mentioned above. Cost or pricing is not a factor.

HCPCS Level II Coding Cycles, Timelines, Deadlines, and Final Decisions

Beginning in 2020, CMS implemented shorter and more frequent coding cycles to further advance its initiative to unleash innovation. Please note, beginning in 2023, HCPCS Level II application submission deadlines will align with the first business day of each quarter (January, April, July and October) for Drugs and Biologicals and first business day of January and July for Non-drug and Non-Biologicals.

Non-Drug and Non-Biological Coding Cycles: no less frequently than bi-annually

2022 Coding Cycle 1 for applications for non-drug and non-biological items: Application
 Deadline: 11:59 PM January 4, 2022
 Publish Preliminary Decisions by: May 2022
 Public Meeting: June 2022 (dates to be announced in Federal Register)
 Publication of Final Decisions: July 2022

2022 Coding Cycle 2 for applications for non-drug and non-biological items: Application
 Deadline: 11:59 PM July 5, 2022
 Publish Preliminary Decisions by: Approximately two weeks prior to the Public Meeting date

Public Meeting: Fall 2022 (dates to be announced in Federal Register)
Publication of Final Decisions: January 2023

HCPCS Level II Public Meetings:

In 2000, Congress passed the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Public Law 106-554. Subtitle D, Section 531(b) of BIPA requires the Secretary to have procedures that permit public consultation for coding and payment determinations for new DME under Medicare Part B of title XVIII of the Social Security Act. Accordingly, CMS will host bi-annual public meetings that provide a forum for interested parties to make oral presentations and/or to submit written comments in response to preliminary HCPCS Level II coding for products where code applications have been submitted using the HCPCS coding revision process. Coding requests for non-drug and non-biological products will make up the majority of applications addressed in these public meetings.

Agenda items for the meetings are published in advance of the public meeting on the HCPCS website at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings>. The public meeting agendas include descriptions of the coding request, the applicant, the name of the product or service, CMS' preliminary HCPCS Level II coding recommendation, and the preliminary Medicare benefit category and payment determinations.

This public meeting forum provides an opportunity for the public to become aware of coding, benefit category, and payment changes under consideration for non-drug and non-biological items, as well as an opportunity for public input into final decisions. See: "Guidelines for Participation in CMS' HCPCS Public Meetings" on CMS' HCPCS website at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings>.

Drugs and Biologicals Coding Cycles: no less frequently than quarterly

2022 Coding Cycle 1 for applications for drugs and biologicals:
Application Deadline: 11:59 PM January 4, 2022
Publication of Final Decisions: April 2022

2022 Coding Cycle 2 for applications for drugs and biologicals:
Application Deadline: 11:59 PM April 1, 2022
Publication of Final Decisions: July 2022

2022 Coding Cycle 3 for applications for drugs and biologicals:
Application Deadline: 11:59 PM July 5, 2022
Publication of Final Decisions: October 2022

2022 Coding Cycle 4 for applications for drugs and biologicals:
Application Deadline: 11:59 PM October 3, 2022
Publication of Final Decisions: January 2023

Changes to CMS' HCPCS Level II Coding Procedures that Enable Quarterly Coding Cycles for Drugs and Biologicals:

CMS' delivery on its important goal and stakeholder requests to implement quarterly coding cycles for drugs and biologicals necessitated procedural changes that balance the need to code more quickly against the amount of time necessary to process applications, as described below.

The availability of final elements of FDA approval is critical to CMS decisionmaking for drug and biological codes, particularly where this shorter coding cycle makes CMS reliant upon having complete application information at the time of the application deadline. Accordingly, in implementing significantly shorter coding cycles, CMS has eliminated the 3-month deadline extension for submission of FDA clearance documentation following the application deadline (as previously offered within the annual coding cycle). Under the newly implemented shorter coding cycles, all required FDA documentation is due by the application deadline. Thus, under this new process, the overall timeframe between FDA approval and HCPCS Level II coding will generally be significantly shorter than in the prior annual coding cycle.

In order to further achieve the additional time savings necessary to implement coding for the vast majority of drugs and biologicals on a quarterly cycle, CMS will not be able to conduct public meetings for coding decisions on drugs and biologicals, but will provide an opportunity for applicants to resubmit the application in a subsequent quarterly coding cycle. This offers an opportunity for individual applicants who are dissatisfied with CMS' coding decisions in one quarterly cycle to immediately reapply in the next or a subsequent quarterly cycle. Thus, the overall timeframe for consideration of successive applications is generally still significantly shorter than the prior, annual coding cycle. Although CMS previously included drug and biological code applications in its HCPCS Public Meeting processes, we believe that the changes above are necessary to allow CMS to provide coding on a quarterly cycle.

Requests for Separate Meetings:

The CMS staff schedules meetings with an interested party, at the party's request, as time permits to discuss the application(s) for possible changes to the HCPCS Level II codes. These meetings are held by teleconference.

These meetings are not related to the public meetings mandated by section 531(b) of BIPA; they are also not decision making meetings or CMS HCPCS Level II Application review meetings.

Final Decisions for All HCPCS Level II Applications:

CMS is responsible for making the final decisions pertaining to requests for additions, deletions, and revisions to the HCPCS Level II codes. These decisions may include:

1. The request to establish a new national code has been approved.
2. The request to revise an existing national code has been approved.

3. The request to discontinue an existing national code has been approved.
4. A change to the national codes has been approved that reflects, completely or in part, the coding request. Examples of circumstances under which a change to coding might reflect, in part, the coding request include the addition of a single new code when the incoming request was to establish a series of related codes (e.g., for different package sizes); or addition of a new code that includes a dose descriptor reflecting the lowest common denominator that could be billed in multiples, as per CMS' longstanding coding convention, when the incoming request specified a different dose descriptor.
5. The request for a new code has not been approved because the scope of the request necessitates that additional consideration be given to the request before CMS reaches a final decision.
6. The request for a new national code has not been approved because there already is an existing code that describes the product.
7. The request for a code has not been approved because the product is not used by health care providers for diagnostic or therapeutic purposes.
8. The request for a code has not been approved because the code requested is for capital equipment.
9. The request for a code has not been approved because the product is an integral part of another service and the code for that service includes the product.
10. The request for a revision to the language that describes the current code has not been approved because it does not improve the code descriptor.
11. The request for a new code has not been approved because the product is not primarily medical in nature.
12. The request for a code has not been approved because the product is used exclusively in the inpatient hospital setting.
13. The request for a code has not been approved because it is inappropriate for inclusion in the HCPCS Level II code set and a request should be submitted independently to another coding authority (e.g., AMA for CPT coding, ADA for CDT coding)

CMS will include the reasoning for reaching its decision, along with the decision.

Any applicant who disagrees with CMS' final HCPCS coding decision may submit a new request in a subsequent coding cycle. Applicants are encouraged to provide any new information that may be helpful in explaining why CMS' prior decision should be changed.

F. AVAILABILITY OF HCPCS LEVEL II UPDATES

As part of CMS' ongoing efforts to improve transparency regarding HCPCS Level II coding decisions and streamline our processes, CMS has implemented additional improvements to the issuance of HCPCS Level II coding decisions. Beginning in 2020, consistent with implementing shorter and more frequent HCPCS Level II coding cycles, CMS began releasing its decisions on all coding actions on a quarterly basis in the same format as CMS previously announced its annual decisions (see timeframes above). These actions are available on CMS' website at <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS>

Each payer effectuates the changes to the code sets on its own timeframes. For Medicare, unless otherwise announced or specified, the changes to the codes sets will become effective as follows:

For Quarterly Cycle 1 Drug and Biological Code Applications:

Effective: July 1, 2022

For Quarterly Cycle 2 Drug and Biological Code Applications and for Biannual Cycle 1 Non-Drug and Non-Biological Code Applications:

Effective: October 1, 2022

For Quarterly Cycle 3 Drug and Biological Code Applications:

Effective: January 1, 2023

For Quarterly Cycle 4 Drug and Biological Code Applications and for Biannual Cycle 2 Non-Drug and Non-Biological Code Applications:

Effective: April 1, 2023

Along with quarterly releases, CMS also publishes narrative statements for the HCPCS Level II coding decisions, which provide additional detailed information, including the topic and background summary of every application; CMS' preliminary HCPCS coding recommendations, where applicable; a summary of primary speaker comments at CMS' HCPCS Public Meetings, where applicable; and CMS' final coding decisions and rationale.

In early 2019, CMS created an intuitive online search feature to identify links to current and prior year's publication of narrative summaries and spreadsheets providing HCPCS Level II application and decision information. CMS also restored previously published information from prior years.

Previously, the information in the narrative summary has also been included in the HCPCS Level II coding decision letters written by CMS and mailed to each individual applicant. To streamline our notification processes, rather than issuing individual decision letters, CMS now refers applicants and other stakeholders to the narrative summary and encourages stakeholders to monitor CMS' HCPCS General Information website at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index> for updates.

[CMS' HCPCS General Information website](#) also includes tools to assist stakeholders in locating files and information regarding the most recent HCPCS Level II update, including a listing of miscellaneous codes (referred to as "Not Otherwise Classified" (NOC)) codes; HCPCS Public

Meeting Agendas, which list applications submitted in the current coding cycle; HCPCS Level II Coding Procedures; Guidelines for Participation in CMS' HCPCS Public Meeting; and notice of CMS' decisions to discontinue HCPCS codes. Electronic updates and instructions that include an updated list of codes and identify which codes have been added, revised, or deleted are sent by CMS to Medicare contractors and state Medicaid agencies.

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